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| APPLICATION NO.                                  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.              |
|--|-------------|----------------------|---------------------|-------------------------------|
| 10/743,080                                       | 12/23/2003  | Atsushi Tomokuni     | 247041US0           | 8103                          |
| 22850  | 7590        | 10/10/2007           | EXAMINER            |                               |
| OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. |             |                      |                     | CHANNAVAJJALA, LAKSHMI SARADA |
| 1940 DUKE STREET                                 |             |                      |                     |                               |
| ALEXANDRIA, VA 22314                             |             |                      |                     |                               |
| ART UNIT   |             | PAPER NUMBER         |                     |                               |
|  |             | 1615                 |                     |                               |
| NOTIFICATION DATE                                |             |                      | DELIVERY MODE       |                               |
| 10/10/2007                                       |             |                      | ELECTRONIC          |                               |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com  
oblonpat@oblon.com  
jgardner@oblon.com

|                              |                          |                   |
|------------------------------|--------------------------|-------------------|
| <b>Office Action Summary</b> | Application No.          | Applicant(s)      |
|                              | 10/743,080               | TOMOKUNI, ATSUSHI |
|                              | Examiner                 | Art Unit          |
|                              | Lakshmi S. Channavajjala | 1615              |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) Responsive to communication(s) filed on 06 July 2007.  
 2a) This action is FINAL. 2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

4) Claim(s) 1-9 and 11-19 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-9 and 11-19 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 4-18-07.

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date, \_\_\_\_\_.  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

Receipt of amendment and remarks dated 7-6-07 and IDS dated 4-18-07 is acknowledged. New claims 11-19 have been added. Claim 10 has been canceled. Claims 1-9 and 11-19 are pending in the instant application.

***Response to Arguments***

Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-9 and 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,602,511 to von Corswant ('511).

'511 teach a non-toxic bicontinuous microemulsion compositions with high solubilizing capacity for compounds that have low solubility. '511 teach that the microemulsions are transparent and are suitable for transdermal applications. '511 states in col.3:

The present microemulsion comprises

- a polar phase containing water and optionally an agent for obtaining isotonic conditions, and one or more components (modifiers) for adjusting the polarity,
- a surfactant film modifier,
- a non-polar phase consisting of at least one pharmaceutically acceptable oil and
- a mixture of a hydrophilic and a hydrophobic surfactant up to 15% by weight of the total microemulsion, preferably 4-12%.

The polar phase modifiers of '511 such as glycerol, mannitol, sorbitol etc. (col. 3), read on the instant water-soluble solvent D. '511 teach oils that are similar to the disclosed oils in the instant invention (col.3 and examples) and further teach surfactant compounds that read on the instant amphiphilic compounds (col. 4). '511 teach that changing the amounts of polar and non-polar phase, and the amounts of modifiers in the polar phase, one can prepare bicontinuous microemulsions (col.4). With respect to the amounts of the individual components, even though '511 do not teach the claimed ranges or the ratios of claim 14, suggest amounts that fall within the claimed percentages (see examples). Therefore, in the absence of any criticality with respect to the claimed broad percentage ranges or the specific ratios, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to optimize the amounts of the surfactants, polar phase components and oil so as to obtain a

transparent bicontinuous microemulsion that is suitable for solubilizing the insoluble compounds.

2. Claims 1-9 and 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4767625 to Mitsumo et al ('625, equivalent of JP 62-53910 cited on PTO-1449 of 4-18-07) in view of US 6,602,511 to von Corswant ('511).

'625 teach a lamella-type single phase liquid crystal composition prepared from a hydrophilic nonionic surfactant, a water soluble hydroxylated compound, an oily material and water, as a cleansing cream that can be readily washed off (abstract). The nonionic surfactant, oil and the water soluble hydroxylated compound (reads on instant water soluble solvent) are described in col.2 (entire column), which are the same compounds as recited in the claims 2, 6-7 and 9. The amounts of the above components are described in col. 3, Lines 40-55, which meet the claimed broad ranges. '625 also teach the claimed HLB values in col. 3, Lines 56-67. '625 do not teach the claimed lipophilic amphiphile.

The teachings of '511 for a bicontinuous microemulsions, to solubilize the compounds having low water solubility have been described above. One of an ordinary skill in the art would have readily recognized that employing a combination of surfactants is known in the art for the preparation of transparent microemulsions that form bicontinuous structures. Accordingly, it would have been obvious for a skilled artisan to include the surfactants such as lecithin, phosphatidyl choline etc., in the composition of '625 with an expectation to solubilize the desired insoluble compounds.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615  
September 30, 2007

  
LAKSHMI S. CHANNAVAJJALA  
PRIMARY EXAMINER